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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,771	11/04/2003	Marlene C. Schwarz	12013/53907	5897

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EXAMINER

LAMB, BRENDA A

ART UNIT	PAPER NUMBER
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1734

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,771

Applicant(s)

SCHWARZ ET AL.

Examiner

Brenda A. Lamb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/09/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 26, 28, 29 and 32-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 26, 28, 29 and 32-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-6, 8 and 36-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Alkan et al.

Alkan et al teaches the design of an apparatus for coating a medical implant. Alkan et al apparatus is comprised of the following elements: a coating area sized to accept medical implants for implantation within the body of a patient; means for

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supplying a coating into the coating area; and a means for suspending the medical implants in the coating area during the coating process which includes a vibration structure comprising an acoustic diaphragm with gas flow structure which directs flow from the compressed air cylinder 6 to the coating area. Alkan et al means for supplying coating is capable of supplying a therapeutic coating since it teaches every positively claimed element of the coating apparatus. Alkan et al's coating area is capable of accepting materials within the scope of the claim. Thus every positively claimed element of the apparatus as set forth in claims 36-41 is taught by Alkan et al. With respect to claims 3-5, Alkan et al shows the design of a coating apparatus is comprised of a coating chamber; a vibration source which includes (elements 4 to 9), a portion of the vibration source is positioned within the coating chamber, the vibration source is an acoustic diaphragm assembly; a source of coating (elements 11-13) which includes a nozzle coupled to a supply of coating, the coating source is positioned to introduce coating into the coating chamber wherein a portion of the vibration source is positioned below the screen 3. Thus every positively claimed element of the apparatus as set forth in claims 3-5 is taught by Alkan et al. With respect to claim 6, the Alkan et al vibration source is capable of suspending a substrate within the scope of claim given Alkan et al teaching that amplitude and frequency of vibration of mesh and velocity of air is adjustable. With respect to claim 8, the same rejection applied to claim 4 is applied here. Alkan et al teaches at column 3 lines 18-25 a controller to control the acoustic diaphragm so as to vibrate the diaphragm at the desired frequency such that the medical device is capable of being suspended in the coating chamber. Alkan et al

apparatus inherently includes a power source to provide the motive force for the loud speaker to work.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alkan et al in view of Holt.

Alkan et al is applied for the reasons noted above. Alkan et al fails to teach a coating filter coupled to the coating chamber. However, it would have been obvious to modify the Alkan et al apparatus by providing a coating filter which is operatively coupled to the coating chamber through the coating nozzle such as taught by Holt for the obvious reason to prevent plugging of the coating nozzle.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alkan et al in view of Wurster 3,253,944.

Alkan et al is applied for the reasons noted above. Alkan et al fails to teach the nozzle is positioned beneath the vibration source. However, it would have been obvious to modify the Alkan et al by arranging the coating nozzle beneath a portion of the Alkan et al vibration source which includes tube 4 as well as beneath the screen 3 since Wurster shows doing so for the taught advantage of coating the tablets as they travel upwardly and out of contact with each other.

Claims 26, 33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wurster 3,253,944 in view of Zingerman et al.

Wurster teaches an apparatus for coating a medical implant comprising:
a coating area sized to accept medical implants for implantation within the body of a patient; a source of coating having an exit point in fluid communication with the coating

area; and a screen (elements 20,22 and 24) positioned at the bottom of the coating area; means for forcing the medical implants to move above the screen during the coating process as shown in Figure 1. Wurster fails to teach the source of coating is therapeutic. However, it would have been prima facie obvious to use as the source of coating in the Wurster apparatus one that can include materials which provide a therapeutic benefit especially since Zingerman teaches coating tablet with materials which can obviously provide a therapeutic benefit. With respect to claim 33, Wurster teaches means for forcing the medical implants to move above the screen during the coating process includes a nozzle. With respect to claim 35, Wurster teaches means for forcing the medical implants to move above the screen during the coating process includes a gas flow structure and the gas flow structure includes air inlet 26.

Claims 26, 32 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkan et al in view of Opalski and Zingerman et al.

Alkan et al is applied for the reasons noted above. Alkan et al teaches an apparatus for coating a medical implant comprising: a coating area sized to accept medical implants for implantation within the body of a patient; a source of coating having an exit point in fluid communication with the coating area; and a screen (element 3) positioned at the bottom of the coating area; means for forcing the medical implants to move above the screen during the coating process as shown in Figure 1. However, it would have been obvious to modify the Alkan et al apparatus to connect the coating nozzle to a source of therapeutic material since Opalski spray coating medical devices

with coating that includes therapeutic agents and other coating components (see column 12 lines 48-49 and lines 1-5) and Zingerman teaches coating tablet with materials which can obviously can provide a therapeutic benefit. With respect to claims 34-35, Alkan et al teaches means for forcing the medical implants to move above the screen during the coating process as shown in Figure 1 includes a vibration source and gas flow structure. Alkan et al shows the vibration source is positioned beneath the coating area and nozzle.

Note the reference used in combination with Carter in the last office action for disclosing that therapeutic materials used on medical devices includes anti-microbial materials was inadvertently misspelled and should have been referred to as Leidner et al and not as Leider et al.

Claims 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter in view of Leidner et al.

Carter teaches the design of an apparatus for treating a medical devices comprising: a treating area for treating the medical devices; a vibration source which includes element 18; a source of treating material, includes elements 70, 72, 74 and 76, having an exit point, opening at end of pump hose 74, in fluid communication with the treating area; and a screen 42 positioned at the bottom portion of the coating area wherein vibration in the treating area occurs in a manner so as to cover or coat the surfaces of the medical device thereby the treating material reads on a coating material and treating area reads on a coating area. Carter teaches the contents of the chamber which includes the medical devices, arranged above the screen, is agitated or moved by

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the vibration from the vibration source thereby reading on applicant's claimed means for forcing medical device to move above the screen during the coating process. Carter's source of treating/coating material is an anti-microbial liquid for medical devices which reads on a source of therapeutic material since Leidner et al teaches at column 8 line 64 to column 9 line 6 that therapeutic materials include a variety of materials including anti-microbial materials. Carter's coating area is sized to accept medical instruments and therefore are sized to accept a medical instrument which includes a medical implants for implantation within the body of a patient.

Claim 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomstrom in view of Leidner et al and Tso et al.

Blomstrom teaches a method and apparatus for spraying substrates arranged on a conveyor belt which oscillates or vibrates, thereby reading on a movable conveyor belt and the conveyor conveys the substrates such that they pass under a series of spray nozzles. Blomstrom teaches the spray nozzles spray canthaxanthin onto the substrate and canthaxanthin is a known antioxidant as taught by Tso et al column 10 at lines 11-13 and antioxidant are a type of therapeutic material as taught by Leidner et al (see Leider et al at column 8 line 64 to column 9 line 6). Therefore the above combination of references reads on newly amend claim 29 which omits the previously claimed screen positioned between the vibration source and coating area and the coating area having an implant entrance and implant exit.

Claim 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomstrom in view of Leidner et al, Tso et al and Korstevedt.

Blomstrom, Leidner et al and Tso et al are applied for the reasons noted above. Blomstrom fails to teach the coating area is a confined space with an entrance and an exit and the conveyor belt urges the substrate from the entrance to the exit of the coating area. However, it would have been obvious that to use as the vibrating conveyor assembly in the Blomstrom process one that includes a traveling vibrating conveyor belt with guide rails thereby providing a confined space above the conveyor belt such as taught by Korstvedt for obvious reason to prevent the coated substrate from falling off the lateral edges of the moving conveyor belt and move the coated substrate on the traveling conveyor belt from the entrance to the exit of the confined space for the obvious reason to enable the substrates to be treated in the additional process steps downstream from the coating process step.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is confusing since it is unclear how the medical device recited at line 3 relates to medical implant coated in claim 29 upon which claim 28 depends.

Applicant's arguments filed on 5/09/2005 have been fully considered but they are not persuasive.

Applicant's argument that Carter fails to teach the means for forcing the medical device to move above the screen during the coating process rather teaches the medical device rests on the screen is found to be non-persuasive. The recitation that the means for forcing the medical device to move above the screen does not exclude contact of the

medical device with the screen as argued by applicant. Carter does not disclose movement of the medical device occurs below the screen and therefore all movement of the medical device occurs above the screen as depicted by Carter thereby reading on a means for forcing the medical device to move above the screen.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

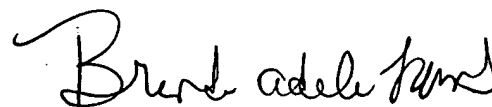
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Lamb whose telephone number is (571) 272-1231. The examiner can normally be reached on Monday and Wednesday thru Friday with alternate Tuesdays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brenda A. Lamb".

BRENDA A. LAMB
PRIMARY EXAMINER